UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

DEFENDANTS' MOTION *IN LIMINE* TO PRECLUDE PLAINTIFFS OR THEIR EXPERTS FROM INTRODUCING EVIDENCE RELATING TO THE FDA WARNING LETTER

Pursuant to Rules 402, 403, and 802 of the Federal Rules of Evidence, Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., Quincy Bioscience Manufacturing, LLC (collectively, "Quincy") and Mark Underwood (together with Quincy, "Defendants") seek to preclude Plaintiffs the Federal Trade Commission (the "FTC") and the New York Attorney General (the "NYAG" and, together with the FTC, "Plaintiffs")[1] and their experts

[1] At the September 15, 2023 pre-trial conference, this Court indicated its view that the FTC should not be permitted to participate in the jury trial on the NYAG's claims, as the FTC is not entitled to

from introducing evidence or eliciting testimony related to a Warning Letter that the FDA issued to Quincy in 2012—five years before the Complaint in this Action was filed—and any correspondence relating to said Warning Letter. Plaintiffs included the Warning Letter and related correspondence on their exhibit list. (*See, e.g.,* Dkt. 299-3, PX-404, PX-405.) Testimony and evidence relating to the Warning Letter is inadmissible for three independent reasons: (i) it is irrelevant to any of the parties' claims or defenses; (ii) it has no probative value and its prejudicial effect will harm Defendants, and (iii) it is hearsay.

In the FDA's own words, an FDA Warning Letter "is informal and advisory." *See* FDA Regulatory Procedures Manual, Subchapter 4-1, available at https://www.fda.gov/media/71878/download (last accessed October 24, 2023). It is the FDA's practice "to give individuals and firms an opportunity to take voluntary and prompt corrective action before [the FDA] initiates an enforcement action." *Id.* The letter "communicates the agency's position on a matter, but it does not commit [the] FDA to taking enforcement action." *Id.* The FDA accordingly "does not consider Warning Letters to be final agency action on which it can be sued." *Id.* In short, warning letters are issued "to achieve voluntary compliance and to establish prior notice." *Id.*

Relevance. The Warning Letter has no relevance here and should be precluded. Any prior notice to Quincy of Plaintiffs' claims is not at issue in this case. The Warning Letter contains only unproven and unsupported allegations relating to Quincy's regulatory compliance (which were later dropped by the FDA)—not to Prevagen's efficacy or the substantiation of Prevagen's marketing claims, which are at the crux of this litigation. Importantly, the FDA never filed an

have a jury decide any of its claims. Defendants agree, and maintain that Mr. Underwood should not be a party to the jury trial as a result, but because this Court has not yet issued a final order on this point, bring this motion on behalf of Quincy and Mr. Underwood, with respect to both the FTC and the NYAG's claims.

enforcement action or took other action with respect to the Warning Letter. Most critically, however, the FDA issued a Close-Out letter with respect to the Warning Letter in 2018—during the pendency of this litigation. (Metzinger Decl.[2] Ex. 1.) In the Close-Out letter, the FDA informed Quincy that it "completed an evaluation of [Quincy's] corrective actions in response to [the] Warning Letter" and that "[b]ased on our evaluation, it appears that [Quincy has] addressed the violations contained the Warning Letter." (*Id*.) While Quincy disagrees that it violated any FDA law or regulation, whatever concerns FDA may have had were obviously resolved by Quincy's responses to the Warning Letter. *See* FDA, About Warning and Close-Out Letters, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters ("A close-out letter will not be issued based on representations that some action will or has been taken. The corrective actions must actually have been made and verified by FDA.") (last accessed October 24, 2023). Because the Warning Letter contains unsubstantiated allegations about outdated statements that are not even relevant to the allegations in this case, and because the FDA subsequently issued a Close-Out letter, testimony and evidence relating to the Warning Letter has no probative value.

Prejudice. Even if the Warning Letter was relevant (it is not), a federal court already excluded testimony and evidence related to *this very* Warning Letter under Rule 403, and this Court should do the same. *See Racies v. Quincy Bioscience, LLC*, No. 15-CV-00292-HSG, 2020 WL 43115, at *6 (N.D. Cal. Jan. 4, 2020) (probative value of *the same* Warning Letter was "substantially outweighed by the danger that the evidence will confuse the issues, mislead the jury, unfairly prejudice Defendant, and waste time"). That is because admission of the Warning Letter

[2] References to the "Metzinger Decl." are to the Declaration of Jaclyn M. Metzinger dated October 24, 2023 and filed herewith.

would be highly prejudicial: as an "official" government report, it "may well carry inordinate weight in the minds of jurors." *Ortho-McNeil-Janssen Pharms., Inc. v. State*, 432 S.W.3d 563, 579 (Ark. 2014) (holding admission of an FDA warning letter was reversible error under Arkansas Rules of Evidence 403 and the advisory commentary to Federal Rule of Evidence 403) (quoting *Boude v. Union Pac. R. Co*., 277 P.3d 1221, 1225 (Mont. 2012)); *see also Smith v. I-Flow Corp*., No. 1:09–CV-03908, 2011 WL 12627557, at *2 (N.D. Ill. June 15, 2011) (excluding FDA warning letter "as irrelevant and under Federal Rule of Evidence 403 due to the potential for unfair prejudice that far outweighs any limited probative value the letter might have regarding the issues the jury will be called upon to decide").

That risk of prejudice is especially applicable here. It appears that Plaintiffs intend to present the Warning Letter at trial in a vacuum. In other words, Plaintiffs intend to introduce the Warning Letter into evidence, while at the same time omitting the FDA's Close Out letter from their exhibit list *and* objecting to Quincy's intended use of the Close Out letter pursuant to FRE 402 and 403. (Dkt. No. 299-4 at DX-369.) As Plaintiffs apparently see it, the FDA's issuance of the Warning Letter is relevant, but the FDA's subsequent decision to close out the Warning Letter is not. Quincy therefore respectfully requests that any testimony or evidence relating to the FDA's Warning Letter be excluded from trial in its entirety. But if the Court finds that testimony and evidence relating to the Warning Letter is admissible, Quincy respectfully requests that the FDA's Close-Out letter and related testimony also be allowed into evidence to avoid jurors being given a prejudicially incomplete version of what transpired with the FDA.

Hearsay. And finally, in addition to being irrelevant and prejudicial, the Warning Letter is hearsay. In *Newman ex rel. Newman v. McNeil Consumer Healthcare*, No. 10 C 1541, 2013 WL 4460011, at *18 (N.D. Ill. Mar. 29, 2013), for example, the Court explained that FDA warning

letters "are inadmissible as hearsay and as irrelevant." Although warning letters are "official agency communications," the FDA "does not intend for them to be final or enforceable." *Id*. at *17. The warning letters in that case therefore were not "factual findings from a legally authorized investigation" and did not fit under the public-records exception to the hearsay rule. *Id*. at *18.

Apart from being informal and nonbinding, the Warning Letter falls outside the scope of the public-records exception to the hearsay rule for another reason: it contains the FDA's legal conclusions. The hearsay exception for public record reaches "factual findings from a legally authorized investigation." Fed. R. Evid. 803(8)(A)(iii). Legal conclusions are not "factual findings." And so, an agency's (or its representative's) legal conclusions are inadmissible even if found in an otherwise-admissible public record. *See Hines v. Brandon Steel Decks*, Inc., 886 F.2d 299, 302-03 (11th Cir. 1989). Such legal conclusions are inadmissible "because the jury would have no way of knowing whether the preparer of the report was cognizant of the requirements underlying the legal conclusion and, if not, whether the preparer might have a higher or lower standard than the law requires." *Id.*; *see also Sullivan v. Dollar Tree Stores, Inc.,* 623 F.3d 770, 777 (9th Cir. 2010) ("Pure legal conclusions are not admissible as factual findings."); *Marten v. Montana,* No. CV 17-31-H-CCL, 2019 WL 4753249, at *3 (D. Mont. Sept. 30, 2019) ("The 'Analysis and Finding' section of the DOJ Report is a legal conclusion and must therefore be excluded."); *Carpenters Health & Welfare Fund v. Coca-Cola Co*., 2008 WL 9358563, at *5 (N.D. Ga. Apr. 23, 2008) ("[L]egal conclusions in public reports are inadmissible." (citing *Hines*)). Plaintiffs should be precluded from introducing the Warning Letter's unsubstantiated legal conclusions into evidence via the Warning Letter.

For these three independent reasons, Defendants respectfully request an Order precluding evidence and testimony relating to the Warning Letter and related correspondence as irrelevant, overly prejudicial, and inadmissible hearsay.

Respectfully submitted,

Dated: October 24, 2023

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